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K070559

## SECTION 5 - 510(K) SUMMARY


Submitter: Polymap Wireless LLC
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JUN 29 2007

Date of Summary: September 15, 2006

Common Name: Accessory to Blood Glucose Meter
Trade Name: PWR-08-03
Classification Name: **Glucose test system.**
Classification No.: **862.1345**

A. Predicate Device

The Polymap PWR-08-03 is substantially equivalent to the e-San Bluetooth Cradle, manufactured by e-San, Ltd., UK.

B. Device Description

The PWR-08-03 is a telemedicine device that uses Bluetooth technology to transmit data from a glucose monitor to compatible access points such as a personal computer or cellular phone with Bluetooth capability. It is connected to the glucose meter by a phono jack and uses short-range low power wireless transmission (Bluetooth VI .2) to send the data to a Bluetooth compatible access point. The unit is battery powered.

C. Intended Use

The Polymap PWR-08-03 is a remote communications link intended to be used to wirelessly transmit glucose meter readings from a Blood Glucose Monitor to a compatible access point or cellular phone, such as the Nokia 6620. The device does not send any real time alarms. Clinical judgment and experience are required to check and interpret the information delivered.

D. Substantial Equivalence Summary

The Polymap PWR-08-03 has indications for use that are identical to those of the named predicate device, the e-San Cradle. The e-San Cradle connects to a LifeScan OneTouch® Ultra® Blood Glucose Monitoring System and sends data from the meter to a Bluetooth compatible access point for transmission to a computer server. This premarket notification has described and compared the characteristics of the Polymap PWR-08-03 to the e-San Cradle in sufficient detail to assure the devices are substantially equivalent.

E. Technological Characteristics

The Polymap PWR-08-03 has technological characteristics that are very similar to those of the e-San Bluetooth Cradle as both are Bluetooth VI.2 compatible. Both devices are battery powered. Each device uses the same frequency band (2.402 to 2.480 GHz).

F. Testing

The testing consisted of three types: bench testing using Polymap procedures and specifications; field testing under actual use conditions; and, performance standards testing. The results were acceptable.

G. Conclusions

This pre-market submission has demonstrated Substantial Equivalence as defined and understood in Sections 513(0(1) and 513(i)(1) of the Federal Food Drug and Cosmetic Act and guidance documents issued by the Center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Polymap Wireless
c/o Dr. Pierre Landau
President
310 S. Williams Blvd, Ste. 346
Tucson, AZ 85711

JUN 29 2007

Re: k070559
Trade/Device Name: Polymap PWR-08-03
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW
Dated: May 08, 2007
Received: May 09, 2007

Dear Dr. Landau:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

## SECTION 4 – INDICATIONS FOR USE

### Indications for Use

**510(k) Number (if known):** K070559

**Device Name: Polymap PWR-08-03**

**Indications For Use:**

The Polymap PWR-08-03 is a remote communications link intended to be used to wirelessly transmit glucose meter readings from a Blood Glucose Monitor to a compatible access point or cellular phone, such as the Nokia 6620. The device does not send any real time alarms. Clinical judgment and experience are required to check and interpret the information delivered.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K070559